UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Biopolymer Engineering, Inc., and
Massachusetts Institute of Technology,

Plaintiffs,

v.

Civil No. 05-536 (JNE/SRN)
ORDER

Immunocorp and Biotec Pharmacon ASA,

Defendants.

Biopolymer Engineering, Inc., and
Massachusetts Institute of Technology,

Plaintiffs,

v.

Civil No. 05-2972 (JNE/JJG)
ORDER

Immudyne, Inc.,

Defendant.

Darren B. Schwiebert, Esq., Fredrikson & Byron, P.A., appeared for Plaintiffs Biopolymer Engineering, Inc., and Massachusetts Institute of Technology.

Susan A. Cahoon, Esq., Bonnie M. Grant, Esq., and Renae A. Bailey, Esq., Kilpatrick Stockton LLP, appeared for Defendants Immunocorp and Biotec Pharmacon ASA.

Kevin D. Conneely, Esq., and David D. Axtell, Esq., Leonard, Street and Deinard, P.A., and John R. Strawn, Jr., Esq., Cruse, Scott, Henderson & Allen, LLP, appeared for Defendant Immudyne, Inc.

Biopolymer Engineering, Inc., and Massachusetts Institute of Technology (collectively, Plaintiffs) assert claims of patent infringement against Immudyne, Inc., Immunocorp, and Biotec Pharmacon ASA (Biotec). The cases are before the Court to construe disputed claim terms pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

I. BACKGROUND

Plaintiffs own or have licenses to U.S. Patent No. 4,992,540 ('540 Patent); U.S. Patent No. 5,037,972 ('972 Patent); U.S. Patent No. 5,576,015 ('015 Patent); U.S. Patent No. 5,702,719 ('719 Patent); U.S. Patent No. 6,020,324 ('324 Patent); U.S. Patent No. 6,143,731 ('731 Patent); U.S. Patent No. 4,962,094 ('094 Patent); U.S. Patent No. 5,532,223 ('223 Patent); U.S. Patent No. 5,811,542 ('542 Patent); U.S. Patent No. 5,849,720 ('720 Patent); U.S. Patent No. 5,622,939 ('939 Patent); U.S. Patent No. 5,817,643 ('643 Patent); U.S. Patent No. 5,622,940 ('940 Patent); and U.S. Patent No. 5,783,569 ('569 Patent). The patents' titles appear below.

'540 Patent	Glucan Composition and Process for Preparation Thereof
'972 Patent	Glucan Composition and Process for Preparation Thereof
'015 Patent	Substantially Purified Beta (1,3) Finely Ground Yeast Cell Wall Glucan Composition with Dermatological and Nutritional Uses
'719 Patent	Substantially Purified Beta (1,3) Finely Ground Yeast Cell Wall Glucan Composition with Dermatological and Nutritional Uses
'324 Patent	Glucan Dietary Additives
'731 Patent	Glucan Dietary Additives
'094 Patent	Glucan Dietary Additives
'223 Patent	Use of Aqueous Soluble Glucan Preparations to Stimulate Platelet Production
'542 Patent	Method for Producing Soluble Glucans
'720 Patent	Enhancement of Non-Specific Immune Defenses by Administration of Underivatized, Aqueous Soluble Glucans
'939 Patent	Glucan Preparation
'643 Patent	Underivatized, Aqueous Soluble ß (1-3) Glucan, Composition and Method of Making Same
'940 Patent	Inhibition of Infection-Stimulated Oral Tissue Destruction by ß(1,3)-Glucan
'569 Patent	Uses for Underivatized, Aqueous Soluble ß(1,3) Glucan and Compositions Comprising Same

Plaintiffs assert claims against Immudyne for infringement of six of the fourteen patents: '540 Patent; '972 Patent; '015 Patent; '719 Patent; '324 Patent; and '094 Patent. Plaintiffs' infringement claims against Immunocorp and Biotec rest on all fourteen patents. In each case, the parties dispute the construction of several claim terms.

II. DISCUSSION

The construction of patent claims "is a matter of law exclusively for the court." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). In construing a claim, the court first looks to "the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The starting point for claim construction is a review of the words of the claims themselves. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc); *Vitronics*, 90 F.3d at 1582 ("First, we look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention."). The words of a claim are generally given their ordinary and customary meaning—the meaning that the term would have to a person of ordinary skill in the art at the time of the invention. *Phillips*, 415 F.3d at 1312-13. "[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. In some cases, the ordinary and customary meaning is readily apparent, and in such cases, general purpose dictionaries may be helpful. *Id*. at 1314. The claims must be read in view of the specification, which is always highly relevant to claim construction. *Id*. at 1315. The specification may provide a special definition given to a claim term or a disavowal of claim scope by the inventor. *Id*. at 1316. The court may not, however,

import limitations found only in the specification. *Id*. at 1323; *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc*., 34 F.3d 1048, 1054 (Fed. Cir. 1994). The court should also consider the patent's prosecution history, which provides evidence of how the United States Patent and Trademark Office and the inventor understood the patent. *Phillips*, 415 F.3d at 1317. The court, in its discretion, may also consider extrinsic evidence, though it is less reliable than intrinsic evidence in construing patent claim terms. *Id*. at 1317-18.

A. Whole glucan

Variations of the words "whole glucan" appear in several claims of the patents-in-suit. The Court considers the variations.

1. '540 Patent and '972 Patent

"Whole glucan particles" and "whole ß-glucan particles" appear in several asserted claims of the '540 Patent and the '972 Patent.[1] For example, claim 1 of the '540 Patent claims "[w]hole glucan particles isolated from glucan-containing cell walls and substantially retaining the in vivo glucan morphology." Claim 2 of the '540 Patent claims "[w]hole glucan particles of claim **1** isolated from yeast cells." Claim 1 of the '972 Patent claims "[a] food formulation containing a glucan comprising whole ß-glucan particles isolated from glucan-containing cell walls and substantially retaining the in vivo glucan morphology." Claim 2 of the '972 Patent claims "[t]he food formulation of claim **1** wherein the whole glucan particles are isolated from yeast cells."

Plaintiffs assert that the Court should construe "whole glucan particles" and "whole ß-glucan particles" as "a glucan derived from yeast that retains the intact cell wall structure from the yeast cell in vivo." Immunocorp and Biotec agree with Plaintiffs' proposed construction.

[1] The '972 Patent issued from a divisional application based on the application that resulted in the '540 Patent; their specifications are essentially the same.

Immudyne proposes the following construction of "whole glucan particles substantially retaining the in vivo glucan morphology" and similar phrases: "a hollow beta-glucan particle that consists entirely of an intact, undisrupted, whole yeast cell wall and that substantially retains the in vivo, three dimensional morphology of the yeast cell." The parties essentially agree that the patentee acted as a lexicographer. *See id.* at 1315-16.

The Court declines to limit "whole glucan particles" or "whole ß-glucan particles" to glucan derived from yeast. Neither the '540 Patent nor the '972 Patent supports the limitation. For example, claim 2 of the '540 Patent, quoted above, reveals that whole glucan particles do not necessarily come from yeast cells. *See id.* at 1314-15. Claim 2 of the '972 Patent, also quoted above, does the same. *See id.* Moreover, the patents' specifications state that "[w]hole glucan particles may be obtained from any glucan-containing source, including yeast or other fungi." '540 Patent, col. 2, ll. 21-23; '972 Patent, col. 2, ll. 20-22.

With regard to "whole glucan particles," the patents' specifications state: "In one embodiment of the present invention, there is provided a glucan derived from yeast which retains the intact cell wall structure of the yeast cell in vivo. Glucan particles having these properties [are] referred to as 'whole glucan particles.'" '540 Patent, col. 2, ll. 13-17; '972 Patent, col. 2, ll. 12-16. The specifications also describe whole glucan particles as the result of an extraction and purification process:

> The process described below for producing the glucan particles can be separated into two steps. The first step involves the extraction and purification of the alkali-insoluble whole glucan particles from the yeast or fungal cell walls. This process yields a product which maintains the morphological and structural properties of the glucan as found in vivo and will be referred to as a whole glucan, or whole glucan particles.

'540 Patent, col. 3, ll. 20-27; '972 Patent, col. 3, ll. 18-25. Consistent with the claim language and the specification, the Court construes "whole glucan particles" and "whole ß-glucan

particles" in the '540 Patent and the '972 Patent as "a glucan derived from a glucan-containing cell that retains the intact cell wall structure of the cell in vivo."

2. '094 Patent

"Whole yeast ß-glucan" appears in several asserted claims of the '094 Patent. For instance, claim 1 states: "A method of providing a source of fiber in the diet of a mammal comprising administering to the mammal an amount of whole yeast ß-glucan sufficient to aid digestion, reduce dehydration or reduce the serum cholesterol level in the mammal." Plaintiffs offer the following construction:

> Glucans which maintain the intact, the three dimensional in vivo morphology of the yeast cells from which they are derived. Whole beta glucans are obtained from yeast cell walls using a purification process which does not disrupt the integrity of the cell walls in the process of extracting the non-glucan components.

Immunocorp and Biotec propose this construction: "Glucan particles from whole yeast cells wherein the walls of the cells are intact and maintain a spherical, elliptical or rod shape characteristic of the beta glucan in the cell wall of a living cell." Immudyne offers the same construction that it proposed in connection with the terms "whole glucan particles" and "whole ß-glucan particles" in the '540 Patent and the '972 Patent.

Plaintiffs assert that the patentee acted as a lexicographer. The Court agrees. Plaintiffs rely on the following passage from the '094 Patent's specification:

> "Whole ß-glucans" are glucans which maintain the intact, the three-dimensional in vivo morphology of the yeast cells from which they are derived. Whole ß-glucans are obtained from yeast cell walls using [a] purification process which does not disrupt the integrity of the cell walls in the process of extracting the non-glucan components.

'094 Patent, col. 3, ll. 8-14. The Court declines to import the method of obtaining whole ß-glucans into the construction of whole yeast ß-glucans. *See Phillips*, 415 F.3d at 1323-24. The Court also declines to import other limitations from the specification identified by the parties.

See id.; *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1308 (Fed. Cir. 2003) ("[V]aried use of a disputed term in the written description attests to the breadth of a term rather than providing a limiting definition."). Accordingly, the Court construes "whole yeast ß-glucan" in the '094 Patent as "glucans which maintain the intact, the three-dimensional in vivo morphology of the yeast cells from which they are derived."

3. '731 Patent

The terms "whole ß-glucan" and "whole yeast ß-glucan" appear in asserted claims of the '731 Patent. For instance, claim 1 states: "A dietary supplement for administration to mammals comprising an amount of whole ß-glucan sufficient to increase high density lipoprotein cholesterol level in said mammal." Claim 9 is: "A method of providing a source of fiber in a diet of a mammal comprising administering to the subject an amount of whole yeast ß-glucan sufficient to increase high density lipoprotein cholesterol level in the mammal." Plaintiffs propose the following construction of whole ß-glucan:

> Glucans which maintain the intact, three dimensional in vivo morphology of the cells from which they were derived. Whole beta glucans are obtained from the cell walls of glucan containing organisms using a purification process, which does not disrupt the integrity of the cell walls in the process of extracting the non-glucan components.

Immunocorp and Biotec offer this construction: "Glucan particles from whole yeast or fungal cells wherein the walls of the cells are intact and maintain a spherical, elliptical or rod shape characteristic of the beta glucan in the cell wall of a living cell."

Plaintiffs assert that the patentee acted as a lexicographer. The Court agrees. The '731 Patent's specification states:

> "Whole ß-glucans" are glucans which maintain the intact, three-dimensional in vivo morphology of the cells from which they are derived. Whole ß-glucans (also referred to herein as "whole glucans") are obtained from the cell walls of glucan-containing organisms using a purification process which does not

> disrupt the integrity of the cell walls in the process of extracting the non-glucan components.

'731 Patent, col. 3, l. 66 to col. 4, l. 5. The Court declines to import the process of obtaining whole ß-glucans or the "spherical, elliptical or rod shape" limitation into the construction of whole ß-glucans. Accordingly, in the '731 Patent, the Court construes "whole ß-glucans" as "glucans which maintain the intact, three-dimensional in vivo morphology of the cells from which they are derived" and "whole yeast ß-glucans" as "glucans which maintain the intact, three-dimensional in vivo morphology of the yeast cells from which they are derived."

4. '324 Patent

"Whole ß-glucan" and "whole yeast ß-glucan" appear in several asserted claims of the '324 Patent. For instance, claim 9 claims "[a] dietary supplement for reducing the level of serum cholesterol in a human or animal consisting essentially of an amount of intact, hollow whole ß-glucan sufficient to reduce the level of serum cholesterol in said human or animal." Claim 13 states: "A method of providing a source of fiber in a diet of a mammal consisting essentially of administering hollow, intact whole yeast ß-glucan to the mammal." Here, the Court concludes that the patentee acted as a lexicographer. The specification states: "'Whole ß-glucans' are glucans which maintain the intact, three-dimensional in vivo morphology of the cells from which they are derived." '324 Patent, col. 3, ll. 58-64. Accordingly, in the '324 Patent, the Court construes "whole ß-glucans" as "glucans which maintain the intact, three-dimensional in vivo morphology of the cells from which they are derived" and "whole yeast ß-glucans" as "glucans which maintain the intact, three-dimensional in vivo morphology of the yeast cells from which they are derived."

B. In vivo morphology

1. '540 Patent and '972 Patent

"Substantially retaining the in vivo glucan morphology," "having substantially the in vivo glucan morphology," and "retaining the in vivo glucan morphology" appear in several asserted claims of the '540 Patent and the '972 Patent. Claim 1 of the '540 Patent and claim 1 of the '972 Patent, quoted above, provide examples of the first phrase's use. Plaintiffs construe "substantially retaining the in vivo glucan morphology" as "the non glucan components (e.g., protein, chitin and glycogen) are extracted from the glucan thereby producing whole glucan particles that have substantially intact cell walls." The portion of Immudyne's proposed construction of "whole glucan particles substantially retaining the in vivo glucan morphology" that relates to the present dispute is "that substantially retains the in vivo, three dimensional morphology of the yeast cell." Immunocorp and Biotec construe "substantially retaining the in vivo glucan morphology" as "substantially and consistently retaining the intact three dimensional structure, typically spherical, of the beta glucan in the cell wall of a living cell." They propose similar constructions of the other phrases.

Beginning with the words of the patents' claims, the Court notes that one claim, claim 9 of the '540 Patent, uses "morphology" to refer to the shape of the whole glucan particles. The claim states: "Whole glucan particles derived from yeast cells, said particles being alkali-insoluble and having substantially the in vivo glucan morphology, said particles also having a spherical morphology with an average particle diameter of from about 2 to about 10 microns and containing greater than 85%, by weight, hexose sugars and less than about one percent, by weight, protein." The claim's reference to a "spherical morphology" suggests that morphology refers to particle shape. *See Phillips*, 415 F.3d at 1314 ("Because claim terms are normally used

consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims."). Although other claims in the '540 Patent and the '972 Patent refer to whole glucan particles being spherical in shape or having a spherical shape, "[d]ifferent terms or phrases in separate claims may be construed to cover the same subject matter where the written description and prosecution history indicate that such a reading of the terms or phrases is proper." *Nystrom v. Trex Co.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005).

The specifications support the suggestion that morphology refers to shape. According to the Background of the Invention, ß-linked glucan "is responsible for the shape and mechanical strength of the cell walls." '540 Patent, col. 1, ll. 38-39; '972 Patent, col. 1, ll. 37-38. The Summary of the Invention indicates that the glucan obtained from the present invention retains the "three dimensional morphology of the intact yeast cell wall":

> By processing yeast cells and the glucans derived therefrom according to the techniques of the present invention, a glucan product which retains the three dimensional morphology of the intact yeast cell wall and having high water holding capacity is formed, which in turn may be further processed to give glucans having improved or novel functional properties.

'540 Patent, col. 2, ll. 6-12; '972 Patent, col. 2, ll. 5-11. "These pure whole glucan particles are typically spherical . . . ." '540 Patent, col. 2, ll. 25-26; '972 Patent, col. 2, ll. 24-25.

The specifications also distinguish morphological properties from structural properties: "This process yields a product which maintains the morphological and structural properties of the glucan as found in vivo . . . ." '540 Patent, col. 3, ll. 24-26; '972 Patent, col. 3, ll. 22-24. In addition, as noted above, ß-linked glucan is responsible for the shape of the cell walls.

The Court turns to the prosecution history. As originally filed, the claims of the '540 Patent did not include the phrase "in vivo glucan morphology." For example, the applicant initially claimed "[g]lucan particles having substantially the three-dimensional structure of glucan in vivo." The examiner rejected the claims "as being clearly anticipated by Manners et

al." At an interview, the examiner and the applicant agreed on the following claim to avoid Manners: "Whole glucan particles isolated from glucan-containing cell walls and substantially retaining their in vivo three dimensional structure." Notwithstanding this agreement, the applicant's amended claim appeared as: "Whole glucan particles isolated from glucan-containing cell walls and substantially retaining the in vivo glucan morphology." The applicant characterized the modification as a "slight change":

> The newly submitted claims are based upon the suggested claim discussed between the Examiner and Applicants' Attorney at the interview. There is a slight change in language relating to the retention by whole glucan particles of the in vivo glucan morphology because one of the inventors . . . believes this to be more scientifically accurate than the previously suggested language stated in terms of the retention of three-dimensional structure.

The amended claims were allowed. During the prosecution of the '972 Patent, the applicant relied on the allowance of the '540 Patent's claims as amended to argue for allowance. The examiner allowed the claims: "The primary reason for allowance of the claims is the requirement thereof that the glucan contained in the food formulation is glucan comprising whole ß-glucan particles isolated from glucan-containing cell walls and substantially retaining the in vivo glucan morphology."

From the words of the claims, the specifications, and the prosecution history, a person of ordinary skill in the art would understand that "in vivo glucan morphology" refers to the shape that the glucan had in the cell from which the glucan is derived. The Court construes "substantially retaining the in vivo glucan morphology" as "substantially retaining the shape that the glucan had in the cell from which the glucan is derived"; "having substantially the in vivo glucan morphology" as "having substantially the shape that the glucan had in the cell from which the glucan is derived"; and "retaining the in vivo glucan morphology" as "retaining the shape that the glucan had in the cell from which the glucan is derived."

2. '094 Patent, '731 Patent, and '324 Patent

As stated above, constructions of "whole ß-glucan" and "whole yeast ß-glucan" in the '094 Patent, '731 Patent, and '324 Patent refer to "three-dimensional in vivo morphology." The patents' specifications reveal that three-dimensional in vivo morphology refers to the shape of the cells from which the glucans are derived. For instance, the detailed descriptions of the inventions state that whole ß-glucan can be derived intact from yeast cell walls. The derivation process "yields intact particles of ß-glucan, which maintain the spherical, elliptical or rod shaped configuration of the ß-glucan as found in vivo." '094 Patent, col. 3, ll. 25-28; '731 Patent, col. 4, ll. 14-16; '324 Patent, col. 4, ll. 4-7. "Whole glucan is comparable in size and shape to whole yeast cells . . . ." '094 Patent, col. 3, ll. 29-31; '731 Patent, col. 4, ll. 17-18; '324 Patent, col. 4, ll. 8-9. The detailed descriptions distinguish structural properties from morphological properties: "Changes in the structure of the yeast cell wall induced by the mutation can then be evaluated for effect on the morphology and structure of the whole ß-glucan extracted from the mutant yeast. These changes may be reflected in the shape of the extracted whole cell walls . . . ." '094 Patent, col. 4, ll. 45-50; '731 Patent, col. 5, ll. 39-43; '324 Patent, col. 5, ll. 31-35. Accordingly, the "three-dimensional in vivo morphology" in constructions of "whole ß-glucan" and "whole yeast ß-glucan" in the '094 Patent, '731 Patent, and '324 Patent refers to the shape of the cells from which the glucans are derived.

C. Hollow

"Hollow" appears in several asserted claims of the '324 Patent. Claims 9 and 13, quoted above, provide examples. After describing the process to obtain whole ß-glucan—extracting non-glucan components without disrupting a cell wall—the '324 Patent's specification states: "These hollow, three-dimensional particles are conducive to a high water holding capacity, in

that they become filled with water upon hydration." '324 Patent, col. 4, ll. 11-13. The '324 Patent's use of "hollow" is consistent with the term's common meaning of having an empty space within. *See Webster's Third New International Dictionary* 1080 (2002). The Court construes the term accordingly. *See Phillips*, 415 F.3d at 1314.

D. Consisting essentially of

The term "consisting essentially of" appears in several asserted claims of the '324 Patent. Claims 9 and 13, quoted above, provide examples. Plaintiffs assert that the claim should be construed as "whole beta-glucan and any other components which do not affect the novel properties of whole beta-glucans." Immudyne contends that the claim should be construed as "consisting entirely of whole beta-glucans and without any non-whole beta-glucans."

Immudyne's proposed construction conflicts with the meaning accorded "consisting essentially of" by the Federal Circuit. *See W.E. Hall Co. v. Atlanta Corrugating, LLC*, 370 F.3d 1343, 1353 (Fed. Cir. 2004); *AFG Indus., Inc. v. Cardinal IG Co.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001); *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). "'Consisting essentially of' is a transition phrase commonly used to signal a partially open claim in a patent." *PPG Indus.*, 156 F.3d at 1354. The phrase typically precedes a list of ingredients in a composition claim or a series of steps in a process claim. *Id.* Use of the phrase signals that "the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *Id.*; *see AFG Indus.*, 239 F.3d at 1245. A claim that uses "consisting essentially of" "occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Indus.*, 156 F.3d at 1354; *see W.E. Hall*, 370 F.3d at 1353.

Immudyne's proposed construction also conflicts with the '324 Patent's specification. *See PPG Indus.*, 156 F.3d at 1355-56. For example, the specification states that the occurrence of non-glucan components is minimized:

> ß-glucans obtained using this process are also very pure. The occurrence of other cell wall components, including glycogen, protein and chitin, is minimized when this process is used. Glycogen, protein and chitin are undesirable as the presence of these components tend to reduce the water holding capacity and the effective dietary fiber content of ß-glucans.

'324 Patent, col. 4, ll. 18-24. Similarly, the specification notes that "[t]he ß-glucan product obtained from this process is typically about 96-99% pure." '324 Patent, col. 4, ll. 39-40. The specification also states that "[t]he composition of the present invention can optionally include, in addition to whole ß-glucan, other components, which will be determined primarily by the manner in which the composition is to be administered." '324 Patent, col. 7, ll. 11-14.

In short, the Court rejects Immudyne's proposed construction of "consisting essentially of." Consistent with the specification and the cases of the Federal Circuit, the Court construes "consisting essentially of" to denote that the claim necessarily includes the listed ingredients or steps and is open to unlisted ingredients or steps that do not materially affect the basic and novel properties of the claim.

E. Without a prior disruption step

"Without a prior disruption step" appears in claim 10 of the '540 Patent, which states: "A process for preparing whole glucan particles having substantially the in vivo glucan morphology, comprising extracting alkali-soluble components from glucan-containing cell[] walls without a prior disruption step for said cell walls to thereby produce whole glucan particles retaining the in vivo glucan morphology." Plaintiffs construe the term as "without a procedure that substantially modifies the cell wall structure of the yeast cell in vivo." Immunocorp and Biotec offer this construction: "Prior to extracting alkali-insoluble components from glucan-

containing cell walls, no other step is performed that would rupture the intact three dimensional structure, typically spherical, of the whole glucan particles." Immudyne construes "without a prior disruption step . . . to thereby produce the in vivo glucan morphology" as "without a process of any kind that would disrupt the intact, whole yeast cell wall which substantially retains the in vivo, three dimensional morphology of the yeast cell."

The Court begins with the language of the claim itself. It suggests that a step that would disrupt cell walls does not precede the extraction of alkali-insoluble components from glucan-containing cell walls. The specification supports this view. The Abstract states: "Three dimensional glucan matrix compositions are prepared by separating growing yeast from its growth medium, subjecting the yeast with cell walls intact to an alkali material, thereby extracting whole glucan particles having an intact cell wall structure." The Summary of the Invention reiterates that the cell walls remain intact: "By processing yeast cells and the glucans derived therefrom according to the techniques of the present invention, a glucan product which retains the three dimensional morphology of the intact yeast cell wall and having high water holding capacity is formed . . . ." '540 Patent, col. 2, ll. 6-10. Similarly, the Detailed Description of the Invention provides: "The process described below for producing the glucan particles can be separated into two steps. The first step involves the extraction and purification of the alkali-insoluble whole glucan particles from the yeast or fungal cell walls. This process yields a product which maintains the morphological and structural properties of the glucan as found in vivo . . . ." '540 Patent, col. 3, ll. 20-26. When the first step is performed, "[t]he yeast should have intact, unruptured cell walls since the preferred properties of the instant whole glucan particles depend upon an intact cell wall." '540 Patent, col. 5, ll. 16-18. "By conducting this [extraction] process without a step of disrupting the cell walls, the extraction can be

conducted at more severe conditions of pH and temperature than was possible with the prior art procedure which included a step of disrupting the cell walls." '540 Patent, col. 6, ll. 3-7. The prosecution history is consistent with the specification's distinction of the prior art:

> [T]he claimed glucan particles are not products of nature but are isolated from glucan-containing cells, such as yeast cells. They are isolated under conditions significantly different from the isolation procedures used by Manners et al. For example, Manners et al. employ pressed Baker's yeast. Applicants have taught, in contradistinction, that yeast cells should be employed without a step of disrupting their cell walls to obtain "whole" glucan particles.

Based on the claim language, the specification, and the prosecution history, the Court construes "without a prior disruption step" to mean "before extracting alkali-insoluble components from glucan-containing cell walls, no step is performed that would disrupt the cell walls."

F. About

The term "about" appears in several claims in many asserted patents. The Court considers the claims in turn.

1. Less than about one percent, by weight, protein

The term "less than about one percent, by weight, protein" appears in claims 6, 8, and 9 of the '540 Patent and claim 5 of the '972 Patent. Claim 8 of the '540 Patent provides an example of the term's use: "Whole glucan particles derived from yeast cells and having substantially the in vivo glucan morphology, said glucan particles containing less than about one percent, by weight, protein and being spherical in shape with an average particle size of from about 2 to about 10 microns." Plaintiffs assert that the term should be construed as "glucan particles containing less than about one percent, by weight, protein." Immudyne contends that the Court should construe the limitation as "1.4% or less, by weight, protein."

The Federal Circuit has repeatedly stated that use of a term such as "about" avoids a "strict numerical boundary to the specified parameter" and that the range "must be interpreted in

its technological and stylistic context." *Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1355-56 (Fed. Cir.), *cert. denied*, 76 U.S.L.W. 3274 (2007); *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326-28 (Fed. Cir. 2007); *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217-18 (Fed. Cir. 1995). Neither the claims nor the specifications illuminate the limit that "about" imparts to "one percent, by weight, protein."[2] No variation from the limitation "less than about one percent, by weight, protein" appears in the '972 Patent's and the '540 Patent's claims. *Cf. Ortho-McNeil Pharm.*, 476 F.3d at 1327. The specifications do not provide a basis to precisely determine the permissible upward deviation from one percent, though they indicate that it is small. Protein is characterized as an "undesirable contaminant[] which affect[s] the biological and hydrodynamic properties of the whole glucan particles." '540 Patent, col. 4, l. 67 to col. 5, l. 2; '972 Patent, col. 4, ll. 65-68. The preferred practice is to remove substantially all protein:

> Preferably, the aqueous hydroxide digestion step is carried out by a series of contacting steps so that the amount of residual contaminants such as proteins are less than if only one contacting step is utilized. In other words, it is desirable to remove substantially all of the protein material from the cell. Preferably such removal is carried out to such an extent that less than one percent of the protein remains with the insoluble cell wall glucan particles. . . . The digested glucan particles can be, if necessary, subjected to further washings and extraction to reduce the protein and contaminant level to the preferred amounts hereinbefore indicated.

'540 Patent, col. 5, l. 52 to col. 6, l. 2; '972 Patent, col. 5 ll. 50-68. Highlighting the purity of the glucan, the specifications later reiterate the claim term:

> The whole glucan particles obtained from the present process are comprised of highly pure glucan, which consists essentially of ß(1-6) and ß(1-3) linked glucan. The whole glucan particles contain very little contamination from protein and glycogen. Preferably, the whole glucan particles . . . contain . . . approximately 1% by weight protein . . . .

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[2] In their reply memorandum, Plaintiffs state: "Nothing in the intrinsic evidence of the '540 and '972 Patents imparts limited meaning to ['about']." Immudyne's reply memorandum, states that "[t]he intrinsic evidence does not compel a non-scientific meaning of 'about.'"

'540 Patent, col. 6, ll. 28-36; '972 Patent, col. 6, ll. 26-34.

Discerning no precise clarification of the meaning "about" in the intrinsic evidence, Immudyne asserts that the Court should apply general rounding principles to construe "about one percent." Immudyne contends that Plaintiffs "should be held to a clearly-defined range of protein" because they "pursu[ed] patent rights" and that Immudyne has "a right to know that the words used in a patent have some meaning." The Court declines to arbitrarily construe the term in the manner proposed by Immudyne:

> Claims are often drafted using terminology that is not as precise or specific as it might be. As long as the result complies with the statutory requirement to "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention," that practice is permissible. That does not mean, however, that a court, under the rubric of claim construction, may give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product. Rather, after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.

PPG Indus., 156 F.3d at 1355 (citation omitted); *see Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir.) ("[A] sound claim construction need not always purge every shred of ambiguity."), *cert. denied*, 76 U.S.L.W. 3253 (2007). Without evidence that would provide a basis to specify the permissible deviation from one percent, the Court gives the term "about" its ordinary meaning of "approximately." *See Merck & Co. v. Teca Pharms. USA, Inc.*, 395 F.3d 1364, 1369-72 & n.7 (Fed. Cir. 2005). Thus, the Court construes "less than about one percent, by weight, protein" as "less than approximately one percent, by weight, protein."

2. Average particle size/diameter of from about 2 to about 10 microns

The term "an average particle size of from about 2 to about 10 microns" appears in claims 7 and 8 of the '540 Patent and claim 6 of the '972 Patent. Claim 8 of the '540 Patent, quoted above, provides an example of the term's use. The term "an average particle diameter of

from about 2 to about 10 microns" appears in claim 9 of the '540 Patent, quoted above. The glucan particles in claims 7, 8, and 9 of the '540 Patent and claim 6 of the '972 Patent are spherical. Plaintiffs propose that the disputed terms be construed as "the glucans have an average diameter of from about 2 to about 10 microns." Immudyne proposes this construction: "The most frequently occurring particle size is from 1.5 to 10.4 microns in diameter."

As to "average," its ordinary meaning is an arithmetic mean. *See Webster's Third New International Dictionary* 118, 150 (2002). The Court rejects Immudyne's construction of "average" as "mode."

With regard to the construction of "about," Plaintiffs and Immudyne essentially repeat their arguments addressed above in connection with "less than about one percent, by weight, protein." The Court does not discern intrinsic evidence that would precisely identify the parameters of the range "about 2 to about 10 microns." No variation from the limitation appears in the '972 Patent's and the '540 Patent's claims. The specifications do not specify the permissible deviations from 2 or 10 microns. The Summary of the Invention gives ranges of particle sizes associated with yeast strains:

> The yeast is preferably a strain of *Saccharomyces cerevisiae*, but any strain of yeast can be used. These pure whole glucan particles are typically spherical, and exhibit a high water holding capacity, as exhibited by their viscosity in aqueous solutions. For example, an aqueous suspension of whole glucan particles derived from strain *Saccharomyces cerevisiae* A364A, having a particle size of approximately 2 to approximately 4 microns containing about 5.5 grams of glucan per deciliter has a viscosity of about 1000 centipoise. A *Saccharomyces cerevisiae* 374 derived glucan, having a particle size of from about 2.5 to about 6.3 microns, has a viscosity of about 2630 centipoise in an aqueous suspension containing about 3.5 grams of glucan per deciliter.

'540 Patent, col. 2, ll. 24-37; '972 Patent, col. 2, ll. 22-35. Later, the Detailed Description of the Invention in the '540 Patent reiterates the claimed range: "Preferably, the whole glucan particles are spherical in shape with a diameter of about 2 to about 10 microns . . . ." '540 Patent, col. 6,

ll. 32-34. In the '972 Patent, the preferred ranges is "about 2 to about 4 microns." '972 Patent, col. 6, l. 32. Without evidence that would provide a basis to specify the permissible deviation from 2 or 10 microns, the Court gives the term "about" its ordinary meaning of "approximately." *See Merck*, 395 F.3d at 1369-72 & n.7. Accordingly, the Court construes "an average particle size of from about 2 to about 10 microns" and "an average particle diameter of from about 2 to about 10 microns" as "the arithmetic mean of the diameters of the particles is approximately 2 to approximately 10 microns."

3. Particle size of about 1.0 micron or less

The parties dispute the construction of limitations regarding particle size that appear in claims 1 and 9 of the '015 Patent and claims 1 and 2 of the '719 Patent. Claim 1 of the '015 Patent is:

> A method for improving the growth and survival of animals comprising:
>
> administering an effective amount of a nutritional supplement to an animal, said nutritional supplement comprising water-insoluble yeast cell wall extract comprising purified beta (1,3) glucan having a particle size of about 1.0 micron or less.

Claim 9 of the '015 Patent claims "[t]he method of claim **1**, wherein said particle size is about 0.20 microns or less." Claim 1 of the '719 Patent is "[a] composition suitable for nutritional supplementation comprising a water-insoluble yeast cell wall extract comprising substantially purified beta (1,3) glucans having a particle size of about 1.0 microns or less." Claim 2 of the '719 Patent claims "[t]he composition of claim **1** having a particle size of about 0.2 microns or less." Plaintiffs contend that the particle size limitations in claim 1 of the '719 Patent and claim 1 of the '015 Patent should be construed as: "The yeast cell wall extract includes beta (1,3) glucan particles that have a particle size of about 1 micron or less." Immunocorp and Biotec propose this construction: "The particles of the cell wall extract are ground to a fine size of

about 1.0 microns or less." Immudyne asserts that the proper construction is "particle size of 1.4 microns or less." Plaintiffs propose this construction for claim 9 of the '015 Patent and claim 2 of the '719 Patent: "The yeast cell wall extract includes beta (1,3) glucan particles that have a particle size of about 0.20 microns or less." Immudyne offers "particle size of 0.24 microns or less."

The intrinsic evidence suggests a narrow construction of "about." The patents' claims include two distinct limitations regarding particle size. Noting that "beta (1,3) glucan may be isolated from yeast cell walls by conventional methods known by those of ordinary skill in the art," the specifications assert that "[a]n improved glucan product is obtained when the average particle size is preferably about 1.0 microns or less, and more preferably about 0.20 microns or less." '015 Patent, col. 2, ll. 25-32; '719 Patent, col. 2, ll. 26-33. The specifications later reiterate the size limitations that appear in the patent claims. Although the Court discerns that "about" has a narrow construction from the intrinsic evidence, there is no evidence that would permit the Court to specify a permissible deviation. Accordingly, the Court declines to arbitrarily construe "about" through use of rounding principles. Instead, the Court gives the term "about" its ordinary meaning of "approximately." *See Merck*, 395 F.3d at 1369-72 & n.7.

As to the proposal of Immunocorp and Biotec regarding grinding, the disputed terms do not explicitly contain a grinding limitation. Accordingly, Immunocorp and Biotec rely on the specifications and prosecution histories to support their proposal. In construing claims, a court must not import limitations from a patent's specification. *In re Trans Tex. Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007); *Phillips*, 415 F.3d at 1323. In general, methods of manufacture disclosed in a specification do not limit product claims:

> It is generally true . . . that product claims are not limited to the methods of manufacture disclosed in the specification and that "[t]he method of

> manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process. . . . A novel product that meets the criteria of patentability is not limited to the process by which it was made." However, process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention.

Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1375 (Fed. Cir. 2007) (citation omitted). Immunocorp and Biotec contend that grinding is critical to the inventions.

Although the specifications of the '015 Patent and the '719 Patent repeatedly refer to "finely ground" or "fine grind" glucan, the specifications reveal that particle size rather than the process of grinding is essential. For instance, the Detailed Description of the Preferred Embodiment(s) states: "To obtain the desired smaller particle size, the mixture comprising the beta (1,3) glucan product is ground down using a blender or ball mill, for example." '015 Patent, col. 2, ll. 33-35; '719 Patent, col. 2, ll. 34-36. Under the subheading "Nutritional Supplementation," the detailed description reveals the benefits of a smaller particle size:

> Both the fine grind and non-ground substantially purified beta (1,3) glucan, more preferably the fine grind glucan described herein, may be administered orally. Finely ground glucan may be administered parenterally. It is believed that upon oral administration, the smaller or finer particle sized glucan is more quickly dissolved in the gastrointestinal tract, and consequently more readily absorbed, as compared to a non-ground glucan product which comprises larger sized glucan particles. Toxic effects have not been detected. It is believed that a fine grind glucan is even more systematically effective than a soluble version. The preferred particle size of the fine grind glucan product is about 1.0 micron or less, and more preferably, 0.20 microns or less.

'015 Patent, col. 2, l. 64 to col. 3, l. 9; '719 Patent, col. 2, l. 65 to col. 3, l. 11.

During the prosecution of the '015 Patent, the examiner rejected claims "as being unpatentable over Schoenherr et al. (MacroGard Publication)":

> Schoenherr et al. disclose the use of Beta 1,3 glucans as a nutritional supplement. The supplement is used as feed an various animals, and includes a teaching of its use on pigs and fish. The feed may be administered either orally or parenterally by injection . . . . Those of ordinary skill would have found it well within their skill to use such an additive on any number of animals given the

> animal models taught therein. However, Schoenherr et al. differs in that the particle size of the Beta 1,3 glucan is not taught.
>
> However, given the general teaching of its art accepted use for the same method of nutritional supplementation, it would have been well within the skill of the ordinary practitioner to claim the instant formulation for its instantly claimed method of nutritional supplementation as taught by Schoenherr et al. Indeed, there are no unusual and/or unexpected results which would rebut the instant prima facie obviousness. It is therefore deemed that it would have been obvious to claim the instant method given the clear teaching of Schoenherr et al. to use beta 1,3-glucans as a nutritional supplement.

(Citations omitted.) The applicant first responded by distinguishing the particle size taught in the MacroGuard publication: "Clearly, the MacroGuard article teaches away from Applicant's invention. The MacroGuard articles teaches a particle size over a thousand times larger than the particle size claimed in the instant application." Summarizing the specification, the applicant next asserted that the application taught finely ground glucan particles, *i.e.*, glucans having a fine particle size. The applicant continued by noting that the prior art does not teach use of particles of such a small size or grinding particles to such a small size. The applicant concluded by highlighting the advantages of use of the smaller particles. The examiner withdrew the obviousness rejection.

During the '719 Patent's prosecution, the examiner rejected claims "as being unpatentable over Jamas et al.":

> Jamas et al. differs in that there is no disclosure of the claimed particle size. However, given the broad disclosure of the glucan particles derived from the yeast cell walls, and administration by the same art recognized routes as disclosed in Jamas et al., those of ordinary skill would have found it within their skill to modify the composition in any art recognized manner which would result in the similar therapeutic effects.

The applicant responded:

> Jamas teaches what has long been believed in the industry, the necessity for a soluble glucan to avoid toxic effects. Jamas repeats the belief of the toxic effects of insoluble glucan products in his specification. Jamas does not teach, disclose or suggest the use of insoluble glucans, of any particle size, for nutritional

> purposes. Jamas did not solve and did not claim to solve the problem of presenting the insoluble molecule effectively in the digestive tract in order to be useful. The industry has long sought solubilizing solutions. Applicant, in contrast, has disclosed uses for a "fine grind" insoluble product that are surprising by their general beneficial effect.
>
> The subject application is the first to teach that there is a particle size such that the insoluble glucan may be used advantageously and beneficially for nutritional purposes. . . .
>
> In conclusion, Jamas does not teach or suggest use of insoluble glucans for nutritional purposes. This is true because Jamas did not appreciate that the insoluble glucan particle size could be limited so as to achieve significant performance in a valuable field where it was otherwise lacking.

The examiner agreed that the applicant's response overcame the rejection.

The Court's review of the specifications and prosecution histories reveals that the particle size itself, not the process of grinding, is essential to the inventions claimed in the '015 Patent and the '719 Patent. Although the specifications do not disclose methods other than grinding to obtain the small particle sizes, the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Phillips*, 415 F.3d at 1323. Accordingly, the Court declines to read grinding into the construction of the disputed terms.

For these reasons, the Court construes "a particle size of about 1.0 micron or less" in claim 1 of the '015 Patent and "a particle size of about 1.0 microns or less" in claim 1 of the '719 Patent as "a particle size of approximately 1.0 micron or less." The Court construes "said particle size is about 0.20 microns or less" in claim 9 of the '015 Patent as "a particle size of approximately 0.20 microns or less." The Court construes "a particle size of about 0.2 microns or less" in claim 2 of the '719 Patent as "a particle size of approximately 0.2 microns or less."

4. About 0.20 mg to about 1.0 mg of said supplement

The term "about 0.20 mg to about 1.0 mg of said supplement" appears in claims 2 and 10 of the '015 Patent. Claim 2 provides an example of the term's use: "The method of claim **1**, wherein said effective amount is from about 0.20 mg to about 1.0 mg of said supplement per 1.0 kg of body weight." Plaintiffs offer this construction: "A yeast cell wall extract in an amount of about 0.20 mg to about 1.0 mg of the nutritional supplement." Immudyne construes the term as "0.15 mg to 1.4 mg of said supplement." There is no evidence that would permit the Court to specify a permissible deviation from 0.20 mg or 1.0 mg. The Court declines to arbitrarily construe "about" through use of rounding principles. Instead, the Court gives the term "about" its ordinary meaning of "approximately." *See Merck*, 395 F.3d at 1369-72 & n.7. The Court therefore construes "about 0.20 mg to about 1.0 mg of said supplement" as "approximately 0.20 mg to approximately 1.0 mg of said supplement."

G. Purified beta (1,3) glucan

The term "purified beta (1,3) glucan" appears in claim 1 of the '015 Patent, quoted above. A similar term, "substantially purified beta (1,3) glucans," appears in claim 1 of the '719 Patent, also quoted above. Plaintiffs construe the terms as "beta (1,3) glucans having predominantly beta (1,3) linkages." Immudyne construes the terms as "pure beta (1,3) glucan that is protein and endotoxin-free."

Plaintiffs support their proposed construction with the following passage from the specifications:

> The present invention is directed to substantially purified, beta (1,3) yeast extract glucans, in particular glucans having a fine particle size, which are useful in both dermatological and nutritional applications. As used herein, the term "substantially purified beta (1,3) yeast extract glucan" refers to a yeast cell wall extract comprising predominantly beta (1,3) glycosidic linkages, as illustrated in Fig. **1**.

'015 Patent, col. 2, ll. 17-23; '719 Patent, col. 2, ll. 17-23.

Immudyne relies primarily on the prosecution history of the '015 Patent to support its proposed construction. Initially, "substantially purified beta (1,3) glucan" appeared in claim 1 of the '015 Patent. The examiner rejected the claim as being vague and indefinite based on the use of "substantially": "There is no particular level of purity which is apparent, and it is suggested that this term be deleted." The applicant responded by asserting that the level of purity was commensurate with that of U.S. Patent No. 5,223,491 ('491 Patent):

> Applicant points to the specification . . . . Therein improved methods for isolating a purified water insoluble beta (1,3) glucan extract are discussed in the inventor's earlier patent, [the '491 Patent]. **This earlier '491 Patent was incorporated by reference in its entirety**. . . .
>
> The level of purity claimed in the instant application is commensurate with the level of priority [sic] claimed in the '491 patent incorporated by reference. Claim 1 of the '491, and all claims that depend therefrom, recite "a substantially purified water insoluble glucan extracted from yeast cell walls . . . ." The '491 Patent, from column 2, line 65 through column 3, line 10, under "Characteristics of Glucan," discusses the preparation of and properties of "purified glucan." E.g. Purified glucan is defined as essentially protein and endotoxin free, and is comprised of polyglucose having predominantly beta 1-3 glucosidic linkages. . . .
>
> Applicant submits that the term "substantially purified" is appropriate in the instant application, as it was appropriate in the inventor's prior issued patent incorporated by reference. Thus, the claims are not rendered "vague and indefinite" by inclusion of the term "substantially." Retaining "substantially" is consistent with the improved beta (1,3) glucan disclosed and claimed.

The applicant's response did not overcome the examiner's rejection:

> Applicant argues that the level of purity is described in parent application '491 which is incorporated by reference in this application. However, nothing in the section recited by applicants correlates "substantially" with these levels of purity. Since applicant has already incorporated the parent application by reference, it is suggested that these characteristics should be added to the instant specification with a sentence which clear[ly] sets out that "substantially" refers to those levels. Since there is nothing in the instant or parent application which . . . would lead those of ordinary skill to equate "substantially" with these or any other levels of purity, the rejection . . . is maintained.

The examiner concluded by stating that "[d]eletion of the term 'substantially' or an amendment clearly indicating that this term should set out a specific amount of purity would place the instant claims in condition for allowance." The applicant responded by deleting "substantially."

By deleting "substantially" instead of defining the term to incorporate the '491 Patent, the applicant declined to do what Immudyne advocates here.[3] Accordingly, the Court concludes that construction of the disputed terms based on the paraphrasing of the '491 Patent's specification in the '015 Patent's prosecution history is not appropriate. *Cf. Pall*, 66 F.3d at 1219-20 ("[W]hen claim changes or arguments are made in order to more particularly point out the applicant's invention, the purpose is to impart precision, not to overcome prior art. Such prosecution is not presumed to raise an estoppel, but is reviewed on its facts, with the guidance of precedent."). Instead, the Court construes the terms based on the specifications. Thus, "substantially purified beta (1,3) glucans" in claim 1 of the '719 Patent means glucans comprising predominantly beta (1,3) glycosidic linkages, and "purified beta (1,3) glucan" in claim 1 of the '015 Patent means glucans comprising beta (1,3) glycosidic linkages.

H. Underivatized, aqueous soluble ß(1,3) glucan

Variations of the phrase "underivatized, aqueous soluble ß(1-3) glucan" appear in several asserted claims of the '720 Patent, the '940 Patent, the '939 Patent, the '223 Patent, the '542 Patent, the '643 Patent, and the '569 Patent. The parties agree that "underivatized" means: "The glucans are not derivatized. Derivatized is a term well recognized by those skilled in the art as a chemical modification made to the glucan moiety, such as methylethers, carboxymethylethers, acetylesters, sulfonylester and phosphoric acid esters."

[3] Immudyne's proposed construction eliminates "essentially" from the alleged definition of "purified glucan."

With respect to "soluble," the parties agree to constructions based on the patents' specifications. Thus, for the '720 Patent, the '940 Patent, the '939 Patent, the '223 Patent, and the '542 Patent, soluble means that "a visually clear solution can be formed in an aqueous medium such as water, PBS, isotonic saline, or a dextrose solution having a neutral pH (*e.g.*, about pH 5 to about pH 7.5), at room temperature (about 20°-25° C) and at a concentration of up to about 10 mg/ml." For the '643 Patent, and the '569 Patent, soluble means:

> A visually clear solution can be formed in an aqueous medium such as water, PBS, isotonic saline, or dextrose solution having a neutral pH (*e.g.*, from about pH 5 to about pH 7.5), at room temperature (about 20°-25° C) and at a concentration of up to about 10 mg/ml, where "visually clear" means that at a concentration of 1 mg/ml, the absorption of the solution at 530 nm is less than OD 0.01 greater than the OD of an otherwise identical solution lacking the ß-glucan component.

I. ß(1,3) glucan of altered carbohydrate structure

The term "ß(1,3) glucan of altered carbohydrate structure" appears in claims 1, 5, 11, 15, and 21 of the '542 Patent. Claim 1 provides an example of its use: "An underivatized, aqueous soluble yeast ß(1-3) glucan derived from glucan particles composed of ß(1-3) glucan of altered carbohydrate structure." Plaintiffs construe "altered" to mean that "the glucan structure has been modified or changed in a manner which endows the altered glucan with properties which are measurably different from those of naturally occurring, unmodified glucan." Immunocorp and Biotec offer this construction of "ß(1,3) glucan of altered carbohydrate structure":

> Beta (1,3) glucan particles derived from glucan whose carbohydrate structure has been modified or changed artificially (genetically, enzymatically, or chemically) to alter the linkages in the glucan, endowing the altered glucan with properties which are measurably different from those of naturally occurring unmodified glucan, so that the altered glucan particles have structural properties which differ from wild-type glucan.

The '542 Patent incorporates by reference U.S. Patent 5,028,703 ('703 Patent), and the parties agree that the '703 Patent defines "altered." The parties differ with respect to how the

'703 Patent defines the term. Two passages from the '703 Patent's specification are particularly relevant. The first states:

> The term "altered" as used herein and applied to the structure of the glucan (i.e., the ß(1-6) or ß(1-3) linkages) shall be construed to mean that the glucan structure has been modified or changed in some way, endowing the altered glucan with properties which are measurably different from those of naturally occurring unmodified glucans.

'703 Patent, col. 2, l. 65 to col. 3, l. 3. The second is:

> The whole glucan particles produced by the present process are altered with respect to whole glucan particles derived from wild type or unmodified, yeast cells. The term "altered" as used herein is meant to indicate whole glucan particles, the structure of which has been artificially changed or manipulated by one of the above techniques, so that the resulting whole glucan particles are different from the particles derived from wild-type yeast. In this process, the glucan-containing cells can be subject to manipulation (e.g., chemical or physical mutagenesis) or the extracted whole glucan particles can be treated to result in the altered whole glucan particles. "Altered" particles generally will have structural properties which differ from wild-type glucan, such as a different proportion of ß(1-6) or ß(1-3) linkages.

'703 Patent, col. 7, l. 56 to col. 8, l. 2. During the '542 Patent's prosecution, the applicant repeatedly referred to the first quote above to define "altered." Accordingly, the Court construes "altered" to mean that the glucan structure has been modified or changed in some way, endowing the altered glucan with properties which are measurably different from those of naturally occurring unmodified glucans.

J. Triple helix conformation

The term "triple helix conformation" appears in several asserted claims of the '939 Patent, the '223 Patent, and the '569 Patent. Claim 1 of the '939 Patent provides an example of its use: "An underivatized, aqueous soluble ß(1-3) glucan in a triple helix conformation having immunostimulating properties which does not stimulate or prime the production of interleukin-1 or tumor necrosis factor or both, in vitro." Plaintiffs propose the following construction of "triple helix conformation": "Conformation that results from the denaturation and reannealing of

aqueous soluble glucan. Furthermore, the conformation results from dissociating the native glucan conformations and reannealing and purifying the resulting triple helical conformation." Immunocorp and Biotec offer this construction:

> The glucan in solution is a unique and predominately triple helical conformation, where the conformation is produced by dissociating the native conformations, re-annealing the glucan molecules into a unique triple helix conformation, and further purifying to remove single helix and aggregated materials. Triple helical conformation means three beta glucan chains wrapped about each other in a spiral, like three strands in a rope are wrapped about each other.

In light of other claims where the process appears, the Court declines to read into "triple helix conformation" the process used to obtain the conformation. The Court concludes that the term has a readily understood meaning such that no construction is necessary.

K. Molecular species being characterized by a triple helix conformation

The term "molecular species being characterized by a triple helix conformation" appears in claim 8 of the '643 Patent, which claims: "An underivatized, aqueous soluble ß(1-3)-glucan consisting essentially of a molecular species which migrates as a single peak when analyzed by gel permeation chromatography, the molecular species being characterized by a triple helix conformation." The proposed constructions are similar to those offered in connection with "triple helix conformation." The Court declines to read the process to produce a triple helix conformation into the term. The Court concludes that the term has a readily understood meaning such that no construction is necessary.

L. Molecular species migrates as a single peak

The term "a molecular species which migrates as a single peak when analyzed by gel permeation chromatography" appears in claim 8 of the '643 Patent, quoted above. Plaintiffs propose this construction: "A molecular species characterized by a triple helix is identified through gel permeation chromatography as a single peak." Immunocorp and Biotec offer:

"Molecular species which migrates as a single peak and does not migrate as multiple peaks when analyzed by gel permeation chromatography." The Court concludes that this term needs no construction.

M. Enhance non-specific defenses

The terms "enhance the non-specific defenses of mononuclear cells or macrophages or both" and "enhancing the non-specific defenses of mononuclear cells or macrophages or both" appear in claim 8 of the '720 Patent. Claim 8 is:

> A method of treating an immunocompromised human or animal comprising administering to said human or animal an amount of an underivatized, aqueous soluble yeast ß(1-3) glucan sufficient to enhance the non-specific defenses of mononuclear cells or macrophages or both in said animal or human, thereby treating said immunocompromised human or animal by enhancing the non-specific defenses of mononuclear cells or macrophages or both.

Plaintiffs assert that the terms do not need construction. Immunocorp and Biotec offer this construction: "Administration of the soluble glucan enhances the non-specific defenses of mononuclear cells or macrophages or both, but does not result in increased body temperature." Immunocorp and Biotec rely on the following passage from the '720 Patent's specification to support their inclusion of the language regarding body temperature:

> Glucan produced by the present method enhances the non-specific defenses of mammalian mononuclear cells and significantly increases their ability to respond to an infectious challenge. The unique property of glucan-macrophage activation is that it does not result in increased body temperatures (i.e., fever) as has been reported with many non-specific stimulants of host defenses. This critical advantage of glucan may lie in the natural profile of responses it mediates in white blood cells.

'720 Patent, col. 5, ll. 33-41. The Court declines to import "but does not result in increased body temperature" into the construction of the disputed terms and concludes that further construction is not necessary.

N. Average molecular weight

Ranges of average molecular weight appear in claims 5 and 6 of the '939 Patent, claim 17 of the '223 Patent, and claims 5 and 15 of the '542 Patent. Claim 5 of the '939 Patent provides an example:

> An underivatized, aqueous soluble ß(1-3) glucan in a triple helix conformation having immunostimulating properties which does not simulate [sic] or prime the production of interleukin-1 or tumor necrosis factor or both, in vitro and having an average molecular weight of from about 30,000 to about 300,000 daltons.

Plaintiffs construe the term "average molecular weight of from about 30,000 to about 300,000 daltons" as: "The soluble beta (1,3) glucan contains soluble glucan molecules that have an average molecular weight of from about 30,000 to about 300,000 daltons." Immunocorp and Biotec construe the term as: "The glucan has an average molecular weight of from about 30,000 to about 300,000 daltons."[4] The Court construes the term as: "The glucan has an average molecular weight of from approximately 30,000 to approximately 300,000 daltons." The same construction applies to the remaining claims, except that the range is "from approximately 30,000 to approximately 500,000 daltons" for claim 6 of the '939 Patent and claim 17 of the '223 Patent, and "from approximately 10,000 to approximately 500,000 daltons" for claims 5 and 15 of the '542 Patent.

III. CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT the disputed claim terms are construed as set forth in this Order.

Dated: December 21, 2007

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge

[4] The parties' proposed constructions for the remaining claims differ by incorporating the weight ranges that appear in the remaining claims.